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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

LANDSMAN, ROBERT S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/481,990

Applicant(s)

LESAGE ET AL.

Examiner

Robert Landsman

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11 is/are allowed.
- 6) ☒ Claim(s) 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 5/25/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Formal Matters

- A. The Amendment dated 5/25/05 has been entered into the record.
- B. Claims 11 and 28 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.
- D. There is no claim 27 listed in the claim set submitted. It appears that claim 27 was previously pending and claim 28 was cancelled. The present claim set reversed these claims.

2. Specification

- A. The objection to the specification has been withdrawn in view of Applicants' amendment to Figure 1C.
- B. The specification is objected to since the Description of Figure 1 should be amended to recite, for example "Figures 1A – 1D represent..."
- C. When a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and a sequence identifier ("SEQ ID NO:X") must be used either in the drawing or in the Brief Description of the Drawings. See MPEP 2422.02. In the instant application, a sequence identifier must be used for the sequences appearing in Figures 1B, 2A and 2B. Appropriate correction is required.

3. Double Patenting

- A. The double patenting rejections over co-pending applications 09/436,265; 09/939,483; 09/939,484 and 09/892,360 will be held in abeyance until allowable subject matter is identified in the present application.

4. Claim Rejections - 35 USC § 101

A. The rejection of claim 28 (previous claim 27) under 35 USC 101 has been withdrawn in view of the fact that the full-length TWIK protein of SEQ ID NO:2, itself, possess utility. Therefore, the invention as a whole possess utility.

5. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. The rejection of claim 28 (previous claim 27) under 35 USC 112, first paragraph, has been withdrawn in view of the fact that the full-length TWIK protein of SEQ ID NO:2, itself, possess utility.

B. Claim 28 (previous claim 27) remains rejected under 35 USC 112, first paragraph, for the reasons already of record on page 3 of the Office Action mailed 11/22/04. Applicants argue that “although the specification states that the claimed derivatives can be made by “modifying or suppressing one or more amino acid residues,” this can be done only “as long as this modification and/or suppression does not modify the functional properties of the TWIK potassium channel of the resultant protein.” Applicants, therefore, argue that proper orientation of the P1, P2 and M1-M4 domains must be properly conserved and placed in the cell membrane for the desired function to be maintained. They further argue that these derivatives can be made and tested.

These arguments have been considered, but are not deemed persuasive. First, according to Figure 1B, it appears that the transmembrane domains are boxed and the pore domains are underlined. The Examiner urges Applicants to confirm this observation. Even if this is true, it appears that these regions only make up approximately 50% of the protein. Applicants are further urged to provide evidence that up to the remaining 50% of the protein can be altered while retaining protein function (i.e. transporting potassium). Applicants argue that the derivatives can be made by modifying or suppressing amino acids as long as this does not modify the protein. This, however, does not provide any evidence that Applicants knew at the time of the invention what residues of the remaining 50% could be altered. Respectfully, the standard for enablement is “make and use” not “make and test.”

5. Claim Rejections - 35 USC § 112, first paragraph

A. The rejection of claim 27 (now claim 28) under 35 USC 112, second paragraph, has been withdrawn in view of Applicants’ amendment to the claim to recite “comprises.”

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A. Claim 28 (previous claim 27) remains rejected under 35 USC 112, second paragraph, for the reasons already of record on page 4 of the Office Action mailed 11/22/04. The claim should be amended to make it certain that the P and M domains are, in fact, those of SEQ ID NO:2. The terms "P1, P2, M1-M4" are simply general terms. Therefore, any derivative can be made and various regions labeled "P1," "M1," etc. The claim should be amended to recite, for example, "transmembrane domains M1, M2, M3 and M4 of SEQ ID NO:2 in the order..." Furthermore, it is noted that nowhere in any of the Figures are the P or M domains labeled.

6. Conclusion

A. Claim 11 is allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

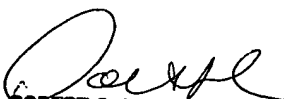
Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 10 AM – 7 PM (eastern); alt F 10 AM – 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert Landsman
Primary Examiner
Art Unit 1647


ROBERT S. LANDSMAN, PH.D.
PRIMARY EXAMINER